Masks are off and everyone wants to put COVID into the rearview mirror…. but not so fast.

COVID gave us the opportunity to try new approaches to trial conduct. We saw that we could do more oversight remotely. We saw that the traditional idea that monitoring can only be done by going to research sites was flawed thinking.

We saw that the traditional dogma requiring research subjects to travel hours to attend research clinic visits in person was the only way to perform research no longer applied.

Today, we have the opportunity to re-evaluate how we perform clinical trials and their oversight. We don't have to perform monitoring (trial oversight) using the same methods we have been using for 30 years—with onsite visits that are hugely expensive and that have a significant impact on global warming. These methods have been proven ineffective.

Dr. Deepak Bhatt from Brigham and Women's Hospital in Boston and I have just published a paper in Contemporary Clinical Trials recommending a systematic evaluation of oversight methods to better understand the sensitivity, specificity, and positive and negative predictive value, for each oversight method that we use: SDV, targeted SDV, statistical outlier identification, key risk indicators, and direct testing of errors that matter.

While this evolution will require cooperative participation from pharma, biotech, and the government to generate the test datasets and funding to evaluate the different methods, the benefit to the industry and to medicine is huge. This new paradigm promises to enhance oversight by testing existing methods of oversight and enabling new methods to be developed and more rapidly adopted, spurring innovation where it is sorely needed.

When all methods are tested in the same environment, Sponsors and regulators can be assured that the methods they choose will find the errors that are most critical to trial integrity. It has the potential to lower monitoring costs by adopting proven monitoring methods that deliver much needed oversight for each specific type of trial.

Because of developments spurred by the pandemic, we have seen innovation that would have taken years to be widely adopted (e.g., telehealth, mRNA vaccines), providing a huge benefit to all of us.

Adopting new methods of oversight may feel somewhat scary, but the payoff is considerable: by using the science that our industry is based on, we can quickly adopt methods that are far more effective and efficient.